



JUL 21 2004

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One Broadway
New York, NY 10004Re: Patent Term Extension
Application for
U.S. Patent No. 5,360,897

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,360,897, which claims the human biologic product PREVNAR® vaccine, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,086 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,086 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 28, 2003 (68 Fed. Reg. 22389). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,648) + 262 \\ &= 1,086 \text{ days}\end{aligned}$$

Since the regulatory review period began November 27, 1994, after the patent issue date (November 1, 1994), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limit of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156 (g)(6) operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,360,897
Granted:	November 1, 1994
Original Expiration Date ¹ :	June 16, 2004
Applicant:	Porter W. Anderson, et al.
Owner of Record:	The University of Rochester

¹Subject to the provisions of 35 U.S.C. § 41(b).

Title: Immunogenic Conjugates of Streptococcus
Pneumoniae Capsular Polymer and Toxin or Toxoid

Classification: 530/403

Product Trade Name: PREVNAR® vaccine (Diphtheria CRM₁₉₇ Protein)

Term Extended: 1,086 days


Expiration Date of Extension: June 7, 2007

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at
(703) 306-3159.


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: PREVNAR®
FDA Docket No. 00E-1403